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|-----------------|-------------|----------------------|---------------------|------------------|
| 10/082,130      | 02/25/2002  | Michael Gerber       | ALL.02              | 1005             |

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EXAMINER

HARTLEY, MICHAEL G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1616

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/082,130

**Applicant(s)**

GERBER, MICHAEL

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 11/29/2004 is acknowledged.

The traversal is on the ground(s) that Groups I and III would not constitute a serious undue burden on the examiner to be searched together, as they appear to be co-extensive. This is found persuasive for Groups I and III only. However, since no other groups have been traversed, the restriction is maintained for all other Groups for the reasons of record. Groups I and III will be combined and examined together herein. The requirement is still deemed proper and is therefore made FINAL.

Claims 7-12 and 20-30 are withdrawn as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

Claims 1-6 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "an allosteric effector compound capable of decreasing hemoglobin binding affinity for oxygen" is not described in a reasonably generic means to show that applicant envisioned all compounds that may have this activity at the time of filing. The specification defines various formulae of compounds that may have this activity, but fails to describe such compounds in a manner to support the definition by function only, as set forth in claims 1 and 13. In the prior art cited by applicant, such allosteric effectors may be various diverse chemical moieties, such as, hydrogen ions, carbon dioxide, 2,3-diphosphoglycerate, etc., (see Steffen, PTO-1449, citation AAC). There is no description in the specification on how hydrogen ions, carbon dioxide, as well as, various other chemical moieties or atoms that may have this function, can be used in the claimed invention. Also, there is no description to generally indicate that applicant envisioned what compounds would and would not have this function to show that applicant envisioned the use of the generic terminology of defining the compound by function only.

The dependent claims fall therewith.

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This rejection can be obviated by incorporating the limitations of claim 2 into claim 1 and claim 14 into claim 13.

***Claim Rejections - 35 USC § 112***

Claims 1-6 and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 13, the recitation of "an allosteric effector compound capable of decreasing hemoglobin binding affinity for oxygen" is indefinite because it is unclear what all compounds are encompassed or excluded thereby. These compounds, as described in the specification, are not specifically limited to certain types of compounds and it is unclear what compounds would be encompassed thereby. Also, this term is not a term of art to specifically define a certain group of compounds with a recognizable genus. One would not be able to recognize if a compound was or wasn't "an allosteric effector compound" as defined, to give a clear meaning of this term. These compounds are defined by function only, and a function which is only present after administration of the compounds. It is unclear what compounds would or would not have this function, other than the compounds of the formulae in the specification.

The dependent claims fall therewith.

This rejection can be obviated by incorporating the limitations of claim 2 into claim 1 and claim 14 into claim 13.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Leunbach (US 5,765,562).

Leunbach discloses a method of measuring blood oxygen level dependent MRI by administration of a free radical compound and performing a blood oxygen level dependent MRI to determine the oxygenation level, see abstract, columns 2-4 and column 10. The oxygenation can be determined for various tissues, such as, tumors, etc., see column 4, lines 27+. The free radical compounds that are administered are shown in columns 9-11 and would inherently be expected to be "capable of" decreasing hemoglobin binding affinity for oxygen as claimed, since these free radical would interact with the iron in hemoglobin which is required for oxygen binding, as supported by the paragraph bridging columns 9-10. Thus, these compounds would inherently be expected to have the function as claimed. It is noted that the recitation of "capable of" is not a positive recitation in any patentable sense, but only requires the ability to so perform. Since the free radicals administered by Leunbach would interact with hemoglobin iron, they would be expected to have the ability to so perform, as claimed.

#### ***Specification***

The disclosure is objected to because of the following informalities: The specification contains two pages numbered as page 9, which are different but co-extensive. The two pages numbered as page 9 contain some of the same text, but are not the same and it is unclear as to why these two pages are present. Appropriate correction is required.

#### ***Allowable Subject Matter***

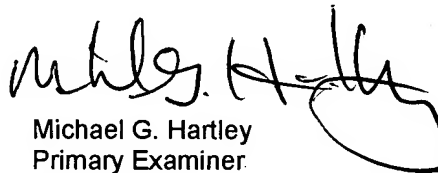
Claims 2-6 and 14-19 are free of the art of record because the prior art fails to teach or suggest the use of compounds as defined by the formulae in these claims in methods of BOLD MRI as claimed. The application can be provisionally placed in condition for allowance by 1) incorporating the limitations of claims 2 and 14 into claims 1 and 13, respectively, 2) canceling all the non-elected claims, i.e., claims 7-12 and 20-30 and 3) correcting the objection to the specification set forth above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

1/3/2005